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| 10/023,205 | 12/14/2001 | Albert Chu | A-70015/DJB | 2654 |

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EXAMINER

PADMANABHAN, KARTIC

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | | |
|-----------------|--------------------|--------------|-------------|
| Application No. | 10/023,205 | Applicant(s) | CHU, ALBERT |
| Examiner | Kartic Padmanabhan | Art Unit | 1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 June 2002.
2a) This action is **FINAL**. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-10 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) Claim(s) _____ is/are allowed.
6) Claim(s) 1-10 is/are rejected.
7) Claim(s) _____ is/are objected to.
8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

DETAILED ACTION

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

2. The disclosure is objected to because of the following informalities: on page 5, applicant has referred to US Pat. 5,885,626, when intending to refer to Pat. 5,885,526. Similarly, on page 8, applicant has referenced Application Number 08/823,436 when intending to refer to 08/823,936. In addition, since this application has since been patented, applicant should refer to the US Patent rather than the application.

Appropriate correction is required. Applicant should also check all other referenced patents and/or applications to make sure they are properly referenced.

3. The use of the trademark InstantChek has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 is rejected as vague and indefinite for the recitation of “capable” because it has been held that the recitation that an element is “capable of” performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

7. Claim 1 is rejected as vague and indefinite for the recitation of “solution first lectin” in step (b) because this terminology is confusing. Should it read “first lectin solution”? In addition, in step (c), applicant has recited that label bound to the reaction membrane is detected, but the label is actually bound to the lectin-carbohydrate complex.

8. Claim 2 is rejected as vague and indefinite for the recitation of “capable” because it has been held that the recitation that an element is “capable of” performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

9. Claim 7 is rejected as vague and indefinite for the recitation of “on at a” because this is grammatically improper. It is unclear where the sample molecule is actually retained. Further, the claim is rejected as vague and indefinite for the recitation of “said one reaction membrane of a second liquid permeable reaction membrane” because it is unclear how many reaction membranes are actually required of the claim, and on which membrane the second discrete region is located.

10. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is the relationship between the step in claim 7, and the rest of the method. In other words, where in the process of claim 1, do the additional steps recited in claim 7 occur?

11. Claim 7 is rejected as vague and indefinite for the recitation of “capable” because it has been held that the recitation that an element is “capable of” performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuber et al. (1997). The reference discloses blot analysis, wherein samples are applied to gels and run.

Nitrocellulose and PVDF membranes are washed and used to form a sandwich with the completed gel. The proteins are electroblotted to the membrane. After the membrane is separated from the gel, it is washed, stained, and destained, after which the membrane is placed in blocking solution. The membrane is then incubated with lectin solution, after which it is washed. It is then incubated with alkaline phosphatase-conjugated anti-DIG antibody, and washed, after which visual detection may occur. Further, controls may be used with the assay. Lectin solution may be incubated with mono or oligosaccharides and used in parallel with sample (page 162-163).

14. Claims 1-2, 6, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chandler (US Pat. 5,998,220). The reference discloses a detection method, wherein a chromatographic medium is used having first and second ends, and a detection zone with an immobilized specific binding partner for binding the analyte to be detected. Sample is applied to the device of the reference, and flows through the chromatographic medium, including the detection zone, such that analyte present in the sample may be bound to the detection zone. A detection reagent is then applied to the assay device, wherein the reagent comprises a component that binds specifically to analyte and moves through the detection zone, such that it gives a detectable indication of the presence of analyte, which is then observed or measured. The detection reagent may comprise a specific binding partner for the analyte labeled with a detectable label, and detection may occur via visible observation (Col. 36). Any number of specific binding partners can be used, including biotin-avidin and lectin-carbohydrate (Col. 11). In addition, as an alternative to the use of a secondary specific binding partner, the first specific binding partner can be conjugated to biotin and an avidin-conjugated label can be used (Col. 30).

The reaction membrane also may include a control zone, separate from the detection zone, with analyte immobilized thereto. In addition, the membrane may also be configured to detect a variety of analytes using multiple detection zones. The detection zone is preferably smaller in area than the chromatographic medium. The assay generally requires no longer than 5 minutes. It is inherent that the membrane is liquid permeable, as sample and other reagents flow through the reaction membrane.

15. Claims 1-2, 5-6, and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Chu et al. (US Pat. 5,006,464). The reference discloses a method for detecting a target substance in a liquid sample comprising using a device with a porous liquid-permeable reaction membrane, wherein one surface has an immobilized receptor capable of directly or indirectly binding the target analyte, said receptor being located in a limited region, such as a dot, of the membrane. The liquid sample and a visibly labeled substance are applied to the membrane, wherein analyte in the liquid binds to the immobilized receptor, which analyte is then bound by the labeled substance, which allows for detection of analyte presence. Multiple dots specifically receptive with different analytes may be used to assay different analytes in the sample (Cols. 2-3). Specific binding pairs for use with the reference include lectins and its specific binding mono, di- or trisaccharide. In addition, avidin, biotin, or antibodies thereto may be used. The membrane may be washed prior to detection.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. Claims 3-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (US Pat. 5,998,220).

Chandler teaches detection methods, as previously discussed under 35 USC 102. However, the reference does not specifically teach the use of a second lectin as the immobilized receptor or washing.

It would have been *prima facie* obvious to use a lectin as the receptor to immobilize the carbohydrate to the membrane because Chandler teaches that any members of a specific binding pair may be used, including lectin-carbohydrate. Therefore, one would have had a reasonable expectation of success in using lectins to both immobilize the carbohydrate to the membrane, as well as bind to the immobilized carbohydrate. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. In addition, it would have been obvious to detect multiple carbohydrates with different lectins since Chandler teaches that multiple detection zones may be used with different receptors for different analytes.

Finally, it would have been obvious to wash the membrane to remove any substances that might contaminate or interfere with the assay results.

19. Claims 3-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (US Pat. 5,006,464).

The reference teaches a method for detecting a target substance in a liquid sample, as discussed above under 35 USC 102. However, the reference does not specifically teach the use of a second lectin as the immobilized receptor.

It would have been *prima facie* obvious to use a lectin as the receptor to immobilize the carbohydrate to the membrane because Chu et al. teach that any members of a specific binding pair may be used, including lectin-carbohydrate. Therefore, one would have had a reasonable expectation of success in using lectins to both immobilize the carbohydrate to the membrane, as well as bind to the immobilized carbohydrate. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. In addition, it would have been obvious to detect multiple carbohydrates with different lectins since Chu et al. teach that multiple detection zones may be used with different receptors for different analytes.

20. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (US Pat. 5,717,778) in view of Watzele et al. (US Pat. 6,218,546 B1).

Chu et al. teach a method for detecting analyte, wherein a liquid sample is applied a substrate having at least one receptor immobilized thereon in a first limited area, said receptor being capable of directly or indirectly biding analyte. A reagent that is capable of binding directly or indirectly to the analyte is then applied to the substrate and generates a color if analyte

is present. The substrate is then illuminated and a digital image is captured. The substrate is preferably porous (Col. 13). In addition, the method may be used to determine multiple analytes, wherein the substrate has immobilized thereon multiple receptor areas (Col. 14). However, the reference does not teach the use of lectins or washing.

Watzele et al. teach the detection of carbohydrates, wherein avidin may be bound to a membrane such as nitrocellulose, and a labeled glycan receptor, such as lectin, is used to isolate the carbohydrate.

It would have been *prima facie* obvious to use lectins as the receptor to detect carbohydrates as taught by Watzele et al. with the method of Chu et al. because one could have detected any desired analyte with the method of Chu et al. with a reasonable expectation of success. Depending on the analyte of interest, one would have known the appropriate receptors to use. In addition, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Further, it would have been obvious to detect multiple carbohydrates with different lectins since Chu et al. teach that multiple detection zones may be used with different receptors for different analytes. Finally, it would have been obvious to wash the membrane to remove any substances that might contaminate or interfere with the assay results.

Conclusion

Claims 1-10 are rejected.

Reference: Mendel-Hartvig is cited as art of interest for teaching flow-through methods for determining analyte presence.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

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06/14/04